

REMARKS

Claims 49, 51-53, 56-58, 61-63, 66-74; 76-78; and 80-83 were pending in this application.

Claims 49, 57, 58, 73, and 74 have been amended. Support for the amendment can be found in the specification as originally filed at page 16, lines 20-24.

Claim 72 has been canceled without prejudice. Applicants reserve the right to prosecute the subject matter of the canceled claim in one or more related continuation, continuation-in-part, or divisional applications.

No new matter has been introduced by this amendment. Claims 49, 51-53, 56-58, 61-63, 66-71, 73-74, 76-78, and 80-83 will be pending upon entry of the present amendment.

THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, BASED ON LACK OF ENABLEMENT SHOULD BE WITHDRAWN

Claims 49, 52-53, 56, 70, 71, 73, 74, 76-78, and 80-83 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly fails to provide sufficient enablement for the claimed compositions. The Examiner rejected the claims because of the unpredictability in the art. In particular, the Examiner contends that the rejection is "not on the basis that the Applicant is not enabled for any vaccine, but that the Applicant is not enabled for the use of the full scope of modified viruses being claimed." (Office Action, mailed July 10, 2006, p. 4). Further, the Examiner states that the application fails to provide any deletions other than deletions of complete open reading frames.

Without making any admissions as to the merits of the basis of this rejection, Applicants have amended the claims to require the deletion of the NS1 gene. Applicants believe that this amendment overcomes the Examiner's concern that the scope of the claims is too broad.

Claims 49 and 51-53, 56-58, 61-63, 66-74, and 76-83 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly fails to provide sufficient enablement. In particular, the Examiner contends that the specification does not provide sufficient enablement for any deletion, again, because of the uncertainty in the art.

First, without making any admissions as to the merits of the basis of this rejection, Applicants have amended the claims to require the deletion of the NS1 gene. Applicants believe that this amendment overcomes the Examiner's concern that the scope of the claims is too broad.

Second, Applicants had previously pointed out that certainty is not the standard because otherwise any experimentation would be undue. See, e.g., *In re Angstadt*, 190 U.S.P.Q. 214 (C.C.P.A. 1976). Applicants' Response of April 6, 2005. In a more recent decision of the Board of Patent Appeals and Interferences ("Board"), the Board applied the principles of *Angstadt* to a biotechnological context. *In re Neuberger & Rabbitts*, 2002 WL 33952578 (B.P.A.I. 2002). The rejected claims in *Neuberger* were directed to chimeric antibodies with (i) certain antigen binding activity; and (ii) a certain biological activity. The Examiner in *Neuberger* had rejected these claims based on lack of predictability. The Board reversed the Examiner's decision because "a requirement for certainty would be incompatible

with any amount of experimentation and therefore incompatible with the standard of enablement.” *Id.* at 3.

Applying the principles of *Angstadt* and *Neuberger* to the present case, it is apparent that the claimed compositions can be produced without undue experimentation in view of the teachings in the specification. As explained in the Spaete Declaration (submitted in Applicants’ response of May 8, 2006), the specification teaches how to produce the mutant viruses and how to test these viruses for their suitability as vaccines. Neither the generation of the mutant viruses nor the tests of these viruses would require anything but routine experimentation.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 112 BASED ON LACK OF WRITTEN DESCRIPTION SHOULD BE WITHDRAWN

Claims 49, 51-53, 55-58, 60-63, and 65-83 are rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement.

Without making any admissions as to the merits of the basis of this rejection, Applicants have amended the claims to require the deletion of the NS1 gene. Applicants believe that this amendment overcomes the Examiner's concern that the scope of the claims is too broad.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

The Rejection Under 35 U.S.C. § 103 Over Murphy Should Be Withdrawn

Claim 72 is rejected under 35 U.S.C. § 103 over U.S. Patent 5,993,824 to Murphy *et al.* ("Murphy"). Solely to expedite the prosecution of the above-identified application and without making any admission as to the merits of the rejection, Applicants have canceled claim 72. Accordingly the rejection of claim 72 under 35 U.S.C. § 103 over Murphy is moot and should be withdrawn.

Provisional Double Patenting

The claims have been provisionally rejected on the ground of non-statutory obviousness-type double patenting over U.S. Patent Application Nos.: 09/724,388;

10/876,113; 10/975,060; and 10/078,900. As this rejection is a provisional rejection, Applicants will not address this rejection at this time.

CONCLUSION

Applicants respectfully request entry and consideration of the foregoing amendments and remarks. No new matter has been introduced. The claims are believed to be free of the art and patentable. Withdrawal of all the rejections and an allowance are earnestly sought.

Respectfully submitted,

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by *Jacqueline Benn*
Laura A. Coruzzi Reg No 43,492

Laura A. Coruzzi 30,742
(Reg. No.)
JONES DAY
222 East 41st Street
New York, New York 10017
Telephone Number: 212-326-3939
Fax Nos.: 212-869-9741/8864